Atty Dkt: 5331-105
Response to Office Action dated September 30, 2009

#### **REMARKS/ARGUMENTS**

Claims 1, 2, 5 and 8-15 are pending in the application. By this Amendment, claims 1 and 8 are amended and claims 3, 4, 6 and 7 are canceled. Reconsideration and withdrawal of the rejections in view of the foregoing amendments and the following remarks is respectfully requested.

### I. <u>CLAIM REJECTIONS</u>

#### A. The Claims Are Allowable Over Scholl

The Office Action rejects claims 1-7, 9-12 and 15 under 35 USC §102(b) over U.S. Patent No. 3,350,329 to Scholl ("Scholl"). The Office Action further rejects claims 1 and 8 under 35 USC §103(a) over Scholl. As noted above, claims 3, 4, 6 and 7 have been canceled. With respect to the remaining claims, the rejections are respectfully traversed.

The Scholl reference discloses coating compositions which are to be used to coat substrates such as paper and cloth, which require low temperature curing in order to avoid scorching. The Scholl reference is specifically directed to coatings which can be formed as aqueous dispersions, to avoid the disadvantages inherent in using organic solvents.

Scholl teaches that the solutions used to form the coatings include shellac, a resin and a latex emulsion. Scholl indicates that thickeners may be added to give the solution a desired viscosity. Scholl mentions many different substances which could be used as the thickener, one of those substances being alginates. Applicant notes that the alginate is only used for the purposes of thickening the solution.

In the only example disclosed in the Scholl reference where alginate is used as a thickener, which is Example 2, the alginate is added to the other materials as a two percent sodium alginate solution. Scholl indicates that the two percent sodium alginate solution comprises approximately fifteen percent of the total weight of the solution (455 total/ 60 parts by weight for the alginate solution). Given that the alginate solution only comprises fifteen percent of the total weight of the mixture, and given that the alginate solution itself only contains two percent alginate, the alginate would comprise a small fraction of one percent of the total weight of the mixture.

Atty Dkt: 5331-105

Response to Office Action dated September 30, 2009

Claim 1 recites an enteric coating formulation comprising an aqueous shellac salt and alginate, wherein the formulation comprises 10-90 percent aqueous shellac salt and between 10-90 percent alginate. Thus, the minimum amount of alginate in the enteric coating formulation would be 10 percent.

Because the Scholl reference fails to disclose or suggest a mixture which contains at least 10 percent alginate, it is respectfully submitted that Scholl cannot be said to anticipate claim 1.

Applicant notes that the Scholl reference is directed to creating a coating for paper or fabric. Scholl never intended for the described coatings to be used as an enteric coating for an orally administrated pharmaceutical or nutraceutical. Thus, one of skill in the art, attempting to create an improved enteric coating would have had no reason to even consult the teachings of Scholl, which is directed to entirely different coatings used for different purposes. However, to the extent one of skill in the art did consult Scholl, it is respectfully submitted that the person of skill in the art would not have been motivated to increase the percentage of alginate in the mixtures disclosed in Scholl.

Scholl only utilizes alginate to provide a desired degree of viscosity. If one were to significantly increase the amount of alginate in the solutions disclosed in the Scholl reference, one would expect that the viscosity of the resulting solution would become too high for the purposes disclosed within Scholl. Thus, Scholl actually teaches away from a mixture having the percentage of alginate recited in claim 1. It is respectfully submitted that the only motivation for changing Scholl's mixtures so that they have enough alginate to satisfy the ranges recited in claim 1 must come from the impermissible use of hindsight, in view of Applicant's invention.

For all the above reasons, it is respectfully submitted that it would not have been obvious to modify the solutions disclosed in Scholl so that they would contain a sufficient amount of alginate to fall within the scope of claim 1. Accordingly, it is respectfully submitted that claim 1 is allowable. Claims 2, 5, 9-12 and 15 depend from claim 1 and are allowable for the same reasons, and for the additional features which they recite. Withdrawal of the rejections in view of the Scholl reference is respectfully requested.

Atty Dkt: 5331-105
Response to Office Action dated September 30, 2009

### B. The Claims Are Allowable Over Kim

The Office Action also rejects claims 1, 2, 5 and 12-14 under 35 USC §102b) over U.S. Patent No. 6,365,148 to Kim et al. ("Kim"). The rejection is respectfully traversed.

The Kim reference describes a granular coating process for stabilizing lactic acid bacteria. Kim teaches that the bacteria load granules can be coating with two different layers which perform different functions. Kim teaches that an aqueous solution containing sodium alginate is first used to coat the bacteria load granules. Next, a solution which may contain shellac in an organic solvent is used to form a second layer on top of the first layer. The second layer containing shellac is intended to act as a controlled release coating. Kim explains that the first layer formed from the aqueous solution of sodium alginate is intended to coat the bacterial load granules to protect them from the effects of the organic solvents used to form the coating layer containing shellac.

Kim does not disclose or suggest mixing both shellac and alginate into a single solution which is then applied as an enteric coating. Also, when the two separate layers are applied, they do not mix together to form a consolidated layer. The two layers are intended to remain separate, which is what allows the first layer to protect the bacterial load granules from the organic solvent used to form the second layer.

In fact, Kim fails to even disclose or suggest forming an aqueous solution containing shellac. In each of the examples provided in Kim where shellac is used to form the second layer, the shellac is dissolved in an organic solvent, rather than an aqueous solution.

For all the above reasons, it is respectfully submitted that Kim fails to disclose or suggest an enteric coating formulation which includes both aqueous shellac salt and alginate in the percentages recited in independent claim 1. Claims 2, 5 and 12-14 depend from independent claim 1 and are allowable for the same reasons, and for the additional features which they recite. Accordingly, withdrawal of the rejection in view of the Kim reference is respectfully requested.

# II. <u>CONCLUSION</u>

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that additional changes would place the application in

Atty Dkt: 5331-105 Serial No. 10/569,798

Response to Office Action dated September 30, 2009

better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

The Commissioner is authorized to charge the undersigned's deposit account #14-1140 in whatever amount is necessary for entry of these papers and the continued pendency of the captioned application.

Respectfully submitted,

NIXON & VANDERHYE P.C.

## /JOHN C. EISENHART/

John C. Eisenhart Attorney Reg. No. 38,128 901 North Glebe Road, 11th Floor Arlington, VA 22203-1808

Telephone: (703) 816-4000 Facsimile: (703) 816-4100